K030392/1/2

510(k) Summary

JUL 21 2003

Trade Name	Sapphire Detachable Coil System
Generic Name	Artificial Embolization Coil
Classification	Class III, 21 CFR 882.5950
Submitted By	Micro Therapeutics, Inc. 2 Goodyear Irvine, California 92618
Contact	Florin Truuvert
Predicate Device	Target Therapeutics' Detachable Platinum Coil (Guglielmi Detachable Coil, GDC)
Device Description	The Sapphire Detachable Coil (SDC) is manufactured from a platinum alloy attached to a positioning wire. The coil is detached by the Sapphire Detachment System (SDS) power supply, which dissolves a small detachment element between the emboliozation coil and the positioning wire. This occurs after desired placement of the coil in the anatomy. The Sapphire coils are manufactured from platinum/iridium alloy wire that is first wound into the primary coil, and then formed into a secondary (spherical or helical) shape. The Sapphire Detachment Coils are manufactured in different shapes and sizes. These coils are available in spherically shaped configurations, as well as, helically shaped configurations of various diameters and lengths.
Indication For Use	The Sapphire™ Detachable Coils are intended for the endovascular embolization of intracranial aneurysms that – because of their morphology, their location, or the patient's general medical condition – are considered by the treating neurosurgical team to be a) very high risk for management by traditional operative techniques, or b) be inoperable. The Sapphire™ Detachable Coils are also intended for the embolization of other neuro vascular abnormalities, such as, arteriovenous malformations and arteriovenous fistulae.

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Testing	The Sapphire Detachable Coil (SDC) series have been tested and evaluated in performance characteristics including: Coil strength, e.g., the force required to deform the coil shape; the ease of delivery as measured by friction when advancing and retracting the coil through various catheters positioned in a simulated tortuosity, and the detachment time. In addition, reliability after fatigue (10 cycles), coil, detachment zone & coil weld tensile strength, delivery wire flexibility, radiopacity and particulate generation were measured and evaluated. The materials of the Sapphire Detachable Coil series were evaluated with respect to compatibility with Magnetic Resonance Imaging. All performance characteristics met the acceptance criteria. All the above tests were performed and evaluated after 1-year simulated aging and met the acceptance criteria. The Sapphire Detachable Coil (SDC) series have been tested and evaluated with respect to packaging, sterile integrity and sterility validation. The Sapphire Detachable Coil series has been validated in animal studies addressing a wide range of performance parameters, including: the ability to move coil within a microcatheter, fluoroscopic visibility of coil ability to position coil in aneurysm, coil reposition-ability, ability to pack the aneurysm sac, ease of use of the detachment system, coil detachment time, detachment reliability & coils stability. The Sapphire Detachment System (SDS) has been tested and evaluated for conductance of current, compliance with its product specifications, detachment reliability, in-vitro and in-vivo, and has met all acceptance criteria. The Sapphire Detachment System has been tested and evaluated for electrical safety, radiated emission, radio disturbance and Electro-Static Discharge immunity. The firmware as part of the Sapphire Detachment System was tested and evaluated with respect to the expression of its modes and states as described in its Design Specifications. All testing demonstrated compliance with the appropriate standard and/or met the acceptance criteria.
Summary of Substantial Equivalence	The Sapphire Detachable Coil System is substantially equivalent to the predicate device, Target Therapeutics' Detachable Platinum Coil (Guglielmi Detachable Coil, GDC) in - Use the same operational principle - Incorporate the same basic design - Have the same intended use - Are packaged and sterilized using similar materials, and processes In summary, the Sapphire Detachable Coil system described in this submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2003

Ms. Florin Truuvert
Regulatory Affairs Manager
Microtherapeutics, Inc.
2 Goodyear
Irvine, California 92618

Re: K030392
Trade/Device Name: Sapphire Detachable Coil System
Regulation Number: 21 CFR 882.5950
Regulation Name: Artificial Embolization Device
Regulatory Class: III
Product Code: HCG
Dated: May 7, 2003
Received: May 8, 2003

Dear Ms. Truuvert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K030392

Indications for Use Statement

510(k) Number (if known): _____

Device Name: Sapphire Detachable Coil System

Indications for Use: The Sapphire™ Detachable Coils are intended for the endovascular embolization of intracranial aneurysms that – because of their morphology, their location, or the patient's general medical condition – are considered by the treating neurosurgical team to be a) very high risk for management by traditional operative techniques, or b) be inoperable. The Sapphire™ Detachable Coils are also intended for the embolization of other neuro vascular abnormalities, such as, arteriovenous malformations and arteriovenous fistulae.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over the Counter Use** _____
(Per 21 CFR 801.109)

Miriam C Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030392